

### **Remarks**

The claims have been amended to clarify and to place them in a format more customary to US patent practice. Support for new claim 7 can be found, for example, at page 7, lines 14-15 of the specification. Support for new claims 8-9 can be found, for example, at page 7, lines 3-7 of the specification. Support for new claims 10-11 can be found, for example, at page 6, lines 9-15 of the specification. Support for new claims 12 can be found, for example, at page 4, line 4 of the specification. Support for new claims 13 can be found, for example, at page 4, lines 9-10 of the specification and on page 2, line 18, for example. Support for new claim 14 can be found, for example, on page 4, line 6 of the specification. Support for new claim 15 can be found in original claim 5, for example. Support for new claim 16 can be found on page 7, line 19, for example. Support for new claim 17 can be found, for example, at page 5, line 17 of the specification. Support for new claim 18 can be found, for example, at page 8, line 10 of the specification. Support for new claim 19 can be found, for example, at page 2, lines 26-29 of the specification. No new matter has been added.

### **Rejections under 35 USC §101/112**

It is believed that the amendments to the claims render the rejections moot. Thus, it is respectfully requested that the rejections under 35 USC §101 and §112 be withdrawn.

### **Rejections under 35 USC §102/103**

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller (WO 02/40991); Claims 4 and 6 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Miller (WO 02/40991) and Claim 2 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Miller in view of prior art cited on pages 1-2 of the specification.

Miller teaches a water standard for a Karl-Fischer titration. The standard of Miller consists of a stable water-containing compound, sodium tartrate dihydrate, bound together with magnesium stearate to form a tablet.

On page 4 of the Office Action the Examiner alleges:

" Miller teaches that it was determined that the combination of sodium tartrate dihydrate with magnesium stearate in the ratio of 95.5:0.5 produced tablets of optimal hardness and with water contents between 0.005-10% by weight, which is the range of water content in prior art, known water calibration standard materials."

This is not correct. Miller teaches sodium tartrate dihydrate with magnesium stearate with ratios of 99.07:0.3 to 99:1. The magnesium stearate binder forms less than 1 % of the mixture. The water content of sodium tartrate dihydrate is 15.66%. Thus, the water content of the final tablet remains nearly the same as the sodium tartrate dihydrate (i.e., 15.50- 15.61 %) and not between 0.005-10% by weight as the Examiner alleges.


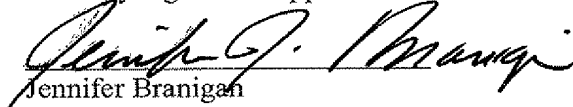
This means that the Miller standard can not be used in the Karl Fischer oven technique which requires a standard with a low water content. See the specification at page 2, lines 10-20, for example. The standard of Miller is used to calibrate volumetric Karl-Fischer measurement devices. Furthermore, the organic water-free component of Miller's standard would decompose at the 140-400 °C oven technique temperature ranges.

Thus, Miller fails to teach or suggest a method for the determination of water wherein the determination is conducted using the Karl Fisher oven technique. Miller is particularly silent regarding a method which utilizes an inorganic stable water-free compound. Furthermore, as the Examiner points out on page 5 of the Office Action, Miller fails to teach that the particle sizes of the water-containing and the water-free components in the calibration standard material are less than 300 micrometers.

For the above reasons it is respectfully requested that the rejections under 35 USC §102/103 be withdrawn.

The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402.

Respectfully submitted,

  
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Attorney Docket No.: **Merck-3122**

Date: **January 22, 2008**  
(Tuesday following a Federal Holiday)

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